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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,553	02/16/2001	Ming-Ming Zhou	2459-1-003 CIP	3124

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/784,553	ZHOU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 9-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Currently, claims 1-36 are pending in the application.
2. In the prior action, mailed on February 22, 2006, claims 5-8 were rejected, and claims 1-4 and 9-36 stood withdrawn as to non-elected inventions. In the Response of May 22, 2005, the Applicant amended claims 6 and 8.
3. Claims 5-8 are under consideration.

#### *Claim Objections*

4. **(Prior Objection- Maintained)** Claims 6 and 8 were objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 8 is treated as representative. The Applicant has amended claims 6 and 8 to read on fusion proteins further comprising the peptides of claims 5 and 7. However, as claims 5 and 7 still read on peptides consisting of SEQ ID NOs: 3 or 19, claims 6 and 8 still fail to further limit these compositions as the fusions of claims 6 and 8 are excluded by the "consisting of" limitations in claims 5 and 7. I.e., the "consisting of" limitation of the independent claims has not been carried through to the dependent claims- thus, the dependent claims are improper. See, MPEP § 608.01(n). The objection is therefore maintained.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

For the purposes of this action, unless otherwise indicated, claims 6 and 8 are treated as though drafted in independent form.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **(New Rejection- Necessitated by Amendment)** Claims 6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims have been amended to read on fusion proteins “further comprising” the isolated peptides of claims 5 or 7, respectively. The claims are rejected because it is not clear what the peptides are included further to. I.e., it is not clear if the claims are intended to read on fusions of two or more proteins and the peptides of claims 5 or 7 in addition thereto, or if the claims are intended to read on fusions comprising the peptide of claims 5 or 7 in addition to another protein or peptide sequence.

Clarification is required.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Maintained)** Claims 5-8 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims read on peptides comprising the ZA loop of protein bromodomains that fall within an indicated generic structure, that of SEQ ID NO: 3. The claims were rejected as the application does not teach how to use the claimed peptides.

The Applicant traverses the rejection on the basis of disclosures in the Declaration of Ming-Ming Zhou regarding knowledge in the art of many bromodomain-containing proteins, knowledge that many of these proteins have been shown to interact with other proteins, and that the function of this interaction is understood for many of these proteins. These arguments are not found persuasive.

It is first noted, as was noted in the prior action, that many of the references referred to in the Zhou declaration were published after the filing date of the current application, and are therefore inappropriate references to rely on to demonstrate what was known (and therefore enabled) at the time of filing.

Further, while the Applicant refers to such teachings, the Applicant presents no arguments to account for the combined uncertainty and breadth of the claims. Even assuming that the indicated references provide certain teachings relating the ability of certain peptides comprising a bromodomain to interact with a peptide comprising an acetylated peptide, the application does not provide sufficient teachings to enable those skilled in the art to use any peptide comprising an acetylated peptide that is capable of interacting with a bromodomain ZA loop, or that those skilled in the art would know how to use the inhibitors of each of such interactions in view of the large variety of protein interactions and functions of such interactions as described in the prior action.

The rejection is therefore maintained for the reasons above, and for the reasons of record.

9. It is noted that the Applicant has presented arguments with respect to written description support of the claimed invention. It is not clear what rejection is being responded to as the written description rejections of record were withdrawn in the prior action.

10. **(New Rejection- Necessitated by Amendment)** Claims 6 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection. As indicated above, claims 6 and 8 have been amended to read on fusion proteins "further comprising" the isolated peptides of claims 5 or 7, respectively. For the purposes of this rejection, the claims are read as describing fusions of two or more proteins to which the peptides of claims 5 or 7 are additionally fused.

While the application provides support for fusion proteins or peptides comprising the indicated peptides of claims 5 or 7, review of the application did not disclose descriptive support for the sub-genus of fusion proteins specifically comprising these peptides fused to a fusion of two or more additional peptides or proteins. The claims are therefore rejected as describing New Matter to the application.

Applicant is requested to either describe where such support may be found, or to cancel the new matter from the claims.

*Claim Rejections - 35 USC § 102*

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. **(Prior Rejection- Maintained)** Claims 6 and 8 were rejected under 35 U.S.C. 102(b) as anticipated by Denis and Green (Genes Dev 10(3): 261-71). The claims and the teachings of Denis and Green have been previously described. The Applicant has amended the claims to read on fusion proteins “further” comprising an isolated peptide of Claim 5 (i.e. has added the term “further” into the claim. It is not clear how this changes the scope of the claim as it is not clear what the peptide of claim 5 is being included further to (i.e., it is not clear what the first protein is). However, as Denis and Green teach a fusion protein comprising a peptide including SEQ ID NO: 19 and a polyhistidine sequence, the reference still anticipates the indicated claims because the sequence of SEQ ID NO: 5 is included further to the polyhistidine sequence.

It is noted that, in retrospect, it is not clear that the suggested claim language in the prior action would have sufficed to overcome the rejection had it been used. Rather, as indicated above, the Applicant would be required to limit the claim language so as not to read on the fusion protein of the cited reference. As this has not been done, the rejection is maintained for the reasons above and the reasons of record.

*Conclusion*

13. No claims are allowed.
14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

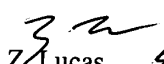
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Z. Lucas 5/31/06  
Patent Examiner



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